PATENT SPECIFICATION

NO DRAWING

1,041,905

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Date of Application and filing Complete Specification: Feb. 11, 1964.
No. 5762/64.
Application made in United States of America (No. 257792) on Feb. 11, 1963.
Complete Specification Published: Sept. 7, 1966.

Index at acceptance:—B6 C(28Q1, 28Q2, A9)

Int. Cl.:—B 41 f

COMPLETE SPECIFICATION

Improvements in or relating to Printing on Discrete Solid Edible Products

We, SMITH KLINE & FRENCH LABORATORIES of 1500 Spring Garden Street, City of Philadelphia, Zone 1, Commonwealth of Pennsylvania, United States of America, a corporation organized under the laws of the Commonwealth of Pennsylvania, one of the United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to a method of printing on discrete solid edible products, particularly but not exclusively solid pharmaceutical dosage forms such as tablets, pills and the like, and to the ink monogrammed products obtained by this method. More particularly, this invention provides a versatile, simplified method of printing on solid pharmaceutical dosage forms which greatly reduces the time previously required.

The technique of the prior art involved in the ink monogramming of tablets has been to apply a preprinting coat of ink receptive material, preferably shellac, over the coated tablets and printing the desired ink indicia thereon. The method of applying the shellac to the pharmaceutical dosage forms is very time consuming. The coated tablets, in particular sugar coated tablets, must be thoroughly dried before the application of the shellac coat in order to prevent frosting of the shellac by the presence of moisture. The method consists of applying the desired tablet coating, removing the tablets from the coating pan after the final color coats have been applied and then drying the tablets overnight in racks. The tablets after being completely dried are then placed in a special shellacking pan and one or more coats of wax free shellac are applied out of a suitable organic solvent, usually isopropyl alcohol. Since this shellac is incompatible with water it is absolutely necessary that the tablets have been thoroughly dried before the application of the shellac. The time required to assure complete drying is approximately 24 hours. The shellac coated tablets are then removed from the shellacking pan, monogrammed and polished.

The method of printing tablets and the like in accordance with this invention eliminates the above time consuming procedure and makes it possible to print tablets rapidly and inexpensively. The time required to print the tablets has been reduced from days to a matter of hours. The method of printing tablets as disclosed herein eliminates the necessity of tablets being dried overnight before the application of the shellac. Another advantage of the method of the invention is that less handling of the tablets is required since they do not have to be racked and repanned for the shellacking step. A further advantage of the method of the invention is that it permits the preprinting coating of the pharmaceutical dosage forms in the same pan in which they are sugar coated thus eliminating the necessity of special shellacking pans. The method of this invention is, therefore, markedly less expensive than those disclosed in the prior art because of the great reduction in operating time and the elimination of the special shellacking pans referred to above.

The method of printing the solid pharmaceutical dosage forms such as compressed tablets, pills, troches and the like in accordance with this invention comprises preparing a preprinting coating solution of a solid non-toxic cellulose derivative in a non-toxic organic solvent in which the derivative is sufficiently soluble. The cellulose coating solution is then applied directly to the solid phar-

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maceutical dosage forms immediately after they have been given their standard coating and gone through the usual drying period and which are being agitated, for example in a coating pan. The cellulose coated tablets are then removed from the coating pan, printed and polished. This method provides for a continuous operation in the coating pan starting with the coating of the medicinal core to the final cellulose coating.

The cellulose coating solution is prepared by dissolving a solid cellulose derivative in an organic solvent advantageously in a concentration of from 1% to 10% weight/volume, preferably from 2% to 5%. The solid cellulose derivative can be any non-toxic, water insoluble, cellulose such as, for example, ethyl cellulose, propyl cellulose, cellulose acetate or cellulose acetate butyrate. The method of this invention is carried out most advantageously by the use of ethyl cellulose.

In accordance with this invention the organic solvent is any non-toxic pharmaceutically acceptable volatile solvent in which the cellulose derivative is sufficiently soluble. Exemplary of such solvents are chloroform, carbon tetrachloride, petroleum ether, benzene, trichloroethylene, ethylene dichloride, and alcohols such as methyl, ethyl or isopropyl alcohol, or mixtures of the above solvents.

The advantageous and preferred preprinting coating solution in accordance with this invention will contain from about 2% to about 5% w/v of ethyl cellulose in chloroform. The coating will be from about 0.01% to about 0.1%, preferably from about 0.01% to about 0.05% of the total tablet weight.

The printing and polishing of tablets referred to above are very well known conventional steps in the tableting art. For example, the printing can be accomplished simply by biasing the tablets against a printing mechanism such as a stamp or roller having the desired monogram and saturated with any of the well known edible inks. Tablet printing machines are available to perform a continuous operation of printing and conveying the tablets, i.e., mass production.

The polishing operation is well known to the art and the materials used may be, for example, beeswax, carnauba wax, ozokerite or ceresine. Preferably a combination of beeswax and carnauba wax in various proportions is used.

The coated tablets referred to in this invention can have any conventional coating well known to the art, such as for example, sugar coating, enteric coating, film coating or any one of the many different forms of sustained release coatings.

The pharmaceutical dosage forms which have been printed using the method of the invention comprise coated tablets, pills, troches and the like substantially surrounded by a coating of a non-toxic cellulosic material and having an ink identifying monogram marked upon a portion of the cellulose coating. If desired, the tablet can be finished with a polishing coat of wax.

While this invention applies mainly to the pharmaceutical industry it is to be understood that this method of printing can be applied to any industry which desires to ink monogram their discrete solid edible products, for example the confectionery industry.

It will also be apparent to those skilled in the pharmaceutical art that methods of coating equivalent to those described hereinbefore could be used, such as, for example, using air suspension, fluid bed or press coating methods.

The following example is illustrative of the method of this invention.

EXAMPLE

Ingredients	Amounts
Ethyl cellulose, N.F. 15 cps	3.0 Gm.
Chloroform	97.0 Gm.

A preprinting coating solution is prepared by dissolving the ethyl cellulose in the chloroform.

Tablet cores containing chlorpromazine and filler are placed in a rotating coating pan and are sugar coated and dried. While continuing to rotate the coating pan the ethyl cellulose solution is then applied to the sugar coated tablets in the rotating pan and allowed to dry. The tablets are then removed from the coating pan and ink monogrammed. A polish coating of beeswax is then applied to the printed tablets.

WHAT WE CLAIM IS:—

1. A method of rendering a discrete solid edible product receptive to the printing thereon of an ink monogram, which method comprises applying to the product a preprinting coating solution comprising a non-toxic cellulose derivative dissolved in a non-toxic organic solvent therefor.

2. A method of rendering a solid pharmaceutical dosage form receptive to the printing thereon of an ink monogram, which method comprises applying to the dosage form a preprinting coating solution comprising a non-toxic cellulose derivative dissolved in a non-toxic organic solvent therefor.

3. A method of ink monogramming a solid pharmaceutical dosage form, which comprises applying to a solid pharmaceutical dosage form having a conventional coating thereon a preprinting coating solution comprising a non-toxic cellulose derivative dissolved in a non-toxic organic solvent therefor, and thereafter ink printing the desired monogram on the preprinting coated dosage form.

4. Method according to Claim 3, which comprises:

(a) applying a conventional coating to the

pharmaceutical dosage form rotating in a coating pan so as to produce conventionally coated dosage forms;

(b) drying said coated forms;

(c) covering said coated forms rotating in the coating pan with the preprinting coating solution to give cellulosic coated pharmaceutical dosage forms; and

(d) ink printing said cellulosic coated pharmaceutical forms with the desired monogram.

5. Method according to Claim 3 or 4, wherein the conventional coating is a sugar coating.

6. Method according to Claim 3, 4 or 5, wherein the ink monogrammed pharmaceutical dosage form is treated with a polishing coat of wax.

7. Method according to any preceding claim, wherein the cellulose derivative employed in the preprinting coating solution is ethyl cellulose.

8. Method according to any preceding claim, wherein the cellulose derivative is present in the preprinting coating solution in a concentration of from 1 to 10% weight/volume.

9. Method according to Claim 8, wherein the concentration is from 2 to 5% weight/volume.

10. A method of ink monogramming a solid pharmaceutical dosage form, substantially as described in the foregoing Example.

11. A monogrammed solid pharmaceutical dosage form whenever produced by the method claimed in any one of Claims 3 to 10.

12. A discrete solid edible product capable of having printed thereon an ink monogram, comprising a solid edible product having a preprinting coating of a non-toxic cellulose derivative.

13. A solid pharmaceutical dosage form capable of having printed thereon an ink monogram, comprising a solid pharmaceutical dosage form having a preprinting coating of a non-toxic cellulose derivative.

14. An ink monogrammed solid pharmaceutical dosage form comprising a conventionally coated solid pharmaceutical dosage form substantially surrounded by a coating of a non-toxic cellulose derivative having an ink monogram printed thereon.

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Leamington Spa: Printed for Her Majesty's Stationery Office by the Courier Press.—1966.
Published at The Patent Office, 25, Southampton Buildings, London, W.C.2, from which copies may be obtained.